

WHAT IS CLAIMED IS:

1. A torqueable sheath which is insertable into a mammalian body and useable to rotationally position of the distal end of a catheter which has been inserted through
5 the sheath; said sheath comprising:

10 a pliable tubular sheath body having a proximal end, a distal end and a hollow lumen extending longitudinally therethrough, said tubular sheath body having sufficient torque strength to transfer torque
15 from the proximal end thereof to the distal end thereof, such that the distal end of the sheath body will rotate in substantial correlation with the proximal end of the sheath body;

20 a catheter engaging surface formed within the lumen of the sheath body, said catheter engaging surface being operative to engage the catheter when the catheter has been inserted through the sheath, such that i) the catheter will be prevented from rotating independently of the introducer sheath, but ii) at least the distal end of the catheter will be caused to rotate in unison with the sheath.

25 2. The torqueable sheath of Claim 1 wherein said tubular sheath body is formed of a polymeric material having reinforcement members disposed therein to increase the torque strength of said polymeric material.

30 3. The torqueable sheath of Claim 2 wherein said reinforcement members are formed into a braid.

35 4. The torqueable sheath of Claim 3 wherein said braid is formed of first and second groups of elongate members, each of said groups of elongate members being made up of a plurality of individual elongate members arranged in substantially parallel, side-by-side relation to one another, said first group being wound about the lumen of the sheath body in a clockwise direction, and said second group being helically wound about the lumen of the sheath

RECORDED - 6/22/01

body in a counterclockwise direction, such that the elongate members of the first group cross with the elongate members of the second group at a plurality of cross-over locations, the individual elongate members of the first group being alternately passed over and under the individual elongate members of the second group at said cross-over locations, so as to form a tubular braid about the lumen of said sheath body.

5. An anchorable guide catheter which is insertable into a luminal anatomical structure, said guide catheter comprising:

10 a elongate catheter body having at least one lumen extending longitudinally therethrough;

15 an opening formed at a first location in said catheter body, in communications with said at least one lumen;

20 a pressure exerting member formed on said catheter body, said pressure exerting member being engageable with the luminal anatomical structure to prevent the first location of the catheter body from moving within the luminal anatomical structure.

6. The anchorable guide catheter of Claim 5 wherein said pressure exerting member is a balloon, and wherein said balloon is inflatable such that it will engage the 25 luminal anatomical structure to prevent the first location of the catheter from moving within said luminal anatomical structure.

7. The anchorable guide catheter of Claim 6 wherein said balloon includes a friction enhancing treatment upon 30 a surface of the balloon which engages the luminal anatomical structure.

8. The anchorable guide catheter of Claim 7 wherein said friction enhancing treatment on said balloon is selected from the group of friction enhancing treatments 35 consisting of:

DOCUMENT EVIDENCE

texturing;
adhesive; and,
woven fabric.

9. The anchorable guide catheter of Claim 5 further
5 comprising:

at least one engagement surface associated with
said first lumen, said at least one engagement surface
being operative to engage a second catheter which has
been inserted through said first lumen such that said
10 second catheter is thereby prevented from rotating
independently of said balloon-anchorable guide
catheter.

10. The anchorable guide catheter of Claim 9 in
combination with at least a) an imaging catheter and b) a
15 passageway-forming catheter having a tissue-penetrating
element which is passable through the wall of the luminal
anatomical structure within which the balloon-anchorable
guide catheter is positioned, said anchorable guide
catheter being useable in conjunction with said imaging
20 catheter and said passageway-forming catheter to form said
passageway through the wall of the luminal anatomical
structure, at a predetermined location, by the following
steps:

25 i) transluminally advancing the guide catheter
into said luminal anatomical structure until the
opening of the guide catheter is near the location on
the luminal anatomical structure through which said
passageway is to be formed;

30 ii) inserting the imaging catheter into a lumen
of the guide catheter such that the imaging catheter
will image anatomical structures which are in
alignment with the opening of the guide catheter;

35 iii) moving the guide catheter until the image
obtained by the imaging catheter indicates that the
opening of the guide catheter is in alignment with the

site at which the extravascular passageway is to be formed;

5 iv) causing the pressure exerting member to engage the luminal anatomical structure 10 as to hold the first location of the guide catheter in substantially fixed position;

10 v) removing the imaging catheter from the first lumen of the guide catheter;

15 vi) inserting the passageway-forming catheter into a lumen of the guide catheter such that the passageway-forming catheter engages the at least one engagement surface of the guide catheter;

15 vii) causing the tissue-penetrating element to pass out of the passageway-forming catheter, through the opening of the guide catheter, and through the wall of the luminal anatomical structure, thereby forming said passageway.

8. The anchorable guide catheter of Claim 7 wherein the pressure exerting member is an inflatable balloon, and wherein the step iv) comprises inflating the balloon such that the balloon will engage the luminal anatomical structure.

9. In a passageway-forming catheter of the type having i) an elongate catheter body and ii) a tissue-penetrating element which is advanceable out of a first location on the elongate catheter body so as to pass through the wall of a luminal anatomical structure and to a target location in which said catheter is positioned, and iii) an imaging means which is useable to image the target location, the improvement comprising:

35 a marker formed on said catheter at a second location, said second location being positioned relative to said imaging means and said first location, such that when the position and rotational orientation of the catheter is adjusted such that said

marker is aimed at said target location, said tissue penetrating element will penetrate through the wall of the luminal structure and into said target location.

10. The catheter of Claim 9 wherein said marker 5 comprises:

a U-shaped member mounted on said catheter.

11. The catheter of Claim 9 wherein said marker comprises:

10 an elongate, generally rectangular member mounted on said catheter.

12. The catheter of Claim 9 wherein said marker comprises:

a elongate wire mounted on said catheter.

13. The catheter of Claim 9 wherein said marker 15 comprises an arcuate member attached to and extending distally from the distal end of the catheter body, said arcuate member being disposed in a plane which is substantially perpendicular to the path of the tissue-penetrating element.

20 14. The catheter of Claim 9 wherein said marker comprises a tripod member mounted on the distal end of the catheter, said tripod member having first second and third legs attached to said catheter and to one another, at least one of said legs being in alignment with the path of the 25 tissue penetrating element.

15. The catheter of Claim 9 wherein the imaging means comprises an elongate imaging lumen which extends longitudinally through the catheter body and into which an imaging apparatus is insertable and positionable so as to 30 obtain an image of said marker and said target anatomical structure.

16. The catheter of Claim 15 wherein said imaging lumen extends longitudinally through the catheter and opens through an outlet aperture in the distal end of the 35 catheter, and wherein said imaging apparatus is advanceable

through said lumen such that the imaging apparatus protrudes out of and extends beyond the distal end of the catheter.

17. The catheter of Claim 15 wherein said imaging 5 lumen extends longitudinally through said catheter and wherein an imaging window is formed at a second location on said catheter such that an imaging apparatus may be advanced through said imaging lumen and utilized to obtain an image of said marker and said target anatomical 10 structure, through said imaging window.

18. The catheter of Claim 9 wherein said catheter further comprises:

15 a flexible tip member mounted on the distal end of the catheter, said flexible tip member having a hollow passageway extending longitudinally therethrough, and wherein said marker comprises an elongate member attached to said catheter body and extending through at least a portion of the hollow passageway formed in said elongate member.

20 19. The catheter of Claim 18 wherein said hollow passageway has a first diameter, and wherein said elongate member has a second diameter smaller than said first diameter, such that a gap surrounds said elongate member within said hollow passageway.

25 20. The catheter of Claim 18 wherein said elongate member protrudes beyond the distal end of said distal tip member.

21. The catheter of Claim 9 wherein said marker comprises:

30 a notch formed within said catheter and surrounded by a plurality of strut members, said imaging means being positionable within said notch, and at least one of said strut members being useable as said marker.

35 22. The catheter of Claim 21 wherein said strut

members comprise elongate wires attached to said catheter body and extending over said notch.

23. The catheter of Claim 21 wherein said notch comprises a region which is cut away from said catheter body such that there is defined a proximal catheter body portion proximal to said notch, and a distal catheter body portion distal to said notch.

24. The catheter of Claim 23 wherein an imaging catheter lumen extends longitudinally through said catheter body, and wherein said imaging means comprises an imaging catheter which is advanceable through said imaging catheter lumen and into said notch such that the image received by said imaging catheter includes the image of said at least one strut member which is useable as said marker.

25. The passageway-forming catheter of Claim 9 wherein said marker is a signal-emitting component which emits a signal which may be detected by said imaging means.

26. The passageway-forming catheter of Claim 25 wherein said energy-emitting component is a piezoelectric crystal.

27. The catheter of Claim 9 wherein the distance from said first location on said catheter to said target anatomical structure is known, and wherein said marker further comprises:

30 a plurality of distance-specific marker locations, each said distance-specific marker location being correlated to a known distance from said first location on said catheter to said target anatomical structure, said imaging means being thereby useable to position a selected one of said distance-correlated markings in alignment with the image of said target anatomical structure, thereby placing the catheter in optimal position and orientation to cause said tissue-penetrating element to form the desired passageway to

said target anatomical structure, without extending beyond said target anatomical structure.

28. A system for positioning/aiming a passageway forming catheter which comprises an elongate catheter body having a tissue-penetrating element passable out of said catheter body in a lateral direction so as to create an interstitial passageway through the wall of the luminal anatomical structure within which the catheter is inserted into a target anatomical location, said apparatus comprising:

an emitting component which causes a signal to be emitted from said target anatomical location; and,

a receiving component which receives said signal from said anatomical location;

15 one of said emitting and receiving components
being located at a fixed position relative to the path
which will be followed by said tissue penetrating
element as said tissue penetrating element passes out
of said catheter, and being thereby useable to
20 position and orient said catheter such that said
tissue-penetrating element will create the desired
interstitial passageway into said target anatomical
location.

29. The system of Claim 28 wherein said emitting
25 component and said receiving component are both located on
said passageway-forming catheter.

30. The system of Claim 28 wherein one of said emitting component and said receiving component is located at said target anatomical location, and the other thereof is located on said passageway-forming catheter.

31. The system of Claim 28 wherein said emitting component comprises an energy-emitting member which emits a form of energy selected from the group of energy forms consisting of:

35 sonic energy;

ultrasonic energy;
light energy;
laser light energy;
radio frequency energy;
5 an electromagnetic signal;

and wherein said receiving component comprises a sensor adapted to receive said form of energy.

32. The system of Claim 28 wherein said emitting and receiving components are respectively positioned such that, 10 when said emitting and receiving components are brought into direct alignment to direct alignment with one another, the passageway-forming catheter will be properly positioned to cause said tissue-penetrating element to pass from said passageway to forming catheter into said target anatomical 15 location, and wherein said system further comprises:

apparatus for monitoring the intensity of the signal received by the receiving component, such that one may determine when the signal received by the receiving component has been peaked, thereby 20 indicating that the emitting and receiving components have been brought into direct alignment with one another and the catheter is correctly positioned and oriented.

33. The system of Claim 32 wherein said apparatus for 25 monitoring the intensity of the signal received by the receiving component comprises in series:

a signal conditioning and filtering component;
a rectifier;
a leaky integrator;
30 a analog to digital converter; and,
a display adapted to display the strength of the signal received by the receiving component.

34. The system of Claim 28 wherein said emitting component comprises an elongate pliable wire having an 35 emission-preventing shield formed laterally about the

length of the wire, with the distal tip of the wire extending out of and beyond said shield such that energy may be emitted by only the distal tip of the wire.

35. The system of Claim 28 adapted for use in a
5 procedure wherein the passageway-forming catheter is
transluminally advanced into a first blood vessel for the
purpose of forming a passageway through the wall of said
first blood vessel and into said target anatomical
location, and wherein one of said emitting and receiving
10 components is insertable into said target anatomical
location and the other thereof is mounted on said
passageway-forming catheter.

36. A system for forming an interstitial passageway which extends through the wall of a luminal anatomical structure, said system comprising:

20 a) a deflectable catheter having an elongate pliable catheter body, a distal end, at least one lumen extending longitudinally through the catheter body, and a distal end opening through which said lumen opens at the distal end of said catheter body, a portion of said catheter body immediately adjacent the distal end thereof being alternately moveable between:

c) a tissue-penetrating element which is advanceable through said at least one lumen of said catheter and out of said distal end opening such that, when the distal portion of the catheter is in its

curved configuration within said luminal anatomical structure, the tissue-penetrating element will pass out of said distal end opening and through the wall of said luminal anatomical structure.

5 37. The system of Claim 36 wherein said catheter further comprises:

10 a marker formed on said catheter at a first location, said marker being positioned at a known location on said catheter and being imagable by said imaging apparatus when said imaging apparatus is inserted into said at least one lumen of said catheter, said marker being thereby useable to facilitate selected rotation orientation of said catheter within said luminal anatomical structure such that, when the distal portion of the catheter is moved to its curved configuration, the distal opening of the catheter will be aimed at a desired location on said luminal anatomical structure.

15 38. The system of Claim 36 wherein said system further comprises:

20 d) a passageway modifying apparatus which is passable through said at least one lumen of said catheter and out of said distal opening, said passageway modifying apparatus being useable to modify a passageway which has been initially formed by said tissue-penetrating element.

25 39. The system of Claim 38 wherein said passageway modifying apparatus is selected from the group of passageway modifying apparatus consisting of:

30 an apparatus for closing said passageway;
an apparatus for stenting said passageway;
an apparatus for enlarging said passageway;
an apparatus for cauterizing said passageway;
an apparatus for placing a channel connector
35 within said passageway;

0951233-00401

an apparatus for blocking the lumen of an anastomized conduit on either side of said passageway to effect flow through said passageway.

40. The catheter of Claim 9 wherein the marker is
5 formed of material which is reflective of energy which is received by the imaging means for the purpose of forming the image.

41. The catheter of Claim 9 wherein the marker is
10 formed of material which is partially internally reflective of energy which is received by the imaging means for the purpose of forming the image.

42. The catheter of Claim 9 wherein the marker is
15 formed of material which is absorptive of energy which is received by the imaging means for the purpose of forming the image.

20

25

30